

REMARKS

By this Amendment the specification has been amended to insert the missing words from page 1, to remove references to specific claims, and to include standard topic headings, and claims 2-17, 19-26, 28, 29 and 30 have been amended to address the examiner's specific objections and to otherwise better conform to U.S. practice. Entry is requested.

In the outstanding Office Action the examiner has rejected claim 28 under 35 U.S.C. 102(b) as being anticipated by Brain '956. The inventors disagree.

Brain '956 discloses a mask with two separate inflatable cuffs which are separately inflatable. A first larger inflatable cuff (10) placed on the bottom side of the mask portion positions and holds the mask in the throat of the patient, while the second inflatable cuff (50) is attached to the top face of the mask, and when inflated applies pressure to the wall of the pharynx opposite a laryngeal opening. It would not be correct to say that Brain '956 has a first cuff which comprises a second cuff.

The mask disclosed in Brain '956 is in contrast to the present invention which has a single inflatable cuff. The inflatable cuff of the present invention is formed such that it comprises inflatable abutment means. When the inflatable cuff is inflated, the inflatable abutment means also inflate.

The second cuff of Brain '956 is arranged to hold a drainage tube in place. The second cuff is arranged as a donut-like shape with the drainage tube placed in the hole of the donut. The second cuff of Brain '956 (which the examiner asserts is equivalent with the inflatable abutment means in the current claim 28) is attached directly to the top face of the mask. It is therefore not possible to provide a passage between the top face of the mask and the second cuff, since the two elements are directly attached together.

In contrast, according to the present invention as defined in claim 28, passages are formed between the inflatable abutment means and the top face of the mask. In this way, it is not necessary to use a drainage tube, since the mask does not block the entire throat of the patient. Instead, a passage is formed on the top face of the mask to allow any fluids to pass the mask. Furthermore, if a drainage tube is desired, then it can be inserted through the passage formed between the inflatable abutment means. It is not necessary to provide for a complicated mask with an integrated drainage tube such as the one disclosed by Brain '956.

The examiner's rejection of claim 28 should be withdrawn.

The examiner has rejected claim 29 under 35 U.S.C. 103(a) as being unpatentable over Brain '956 in view of Brain '790. This rejection is also incorrect.

Brain '790 discloses a top face of a mask portion which includes a lateral bellows 31; the lateral bellows is not part of an inflatable cuff. There is no direct connection between the cuff 30 and the second inflatable means 31.

It is noted that according to the description of Figures 28 and 29 in Brain '790, the item which the examiner calls the lateral bellows (31) is actually a foil sheet which is attached to the "tent" portion (the "tent" seems to be a cover portion which covers the tubes) of the mask. In particular, the foil sheet is described as a cushion in the text and is clearly meant to provide pressure against the back surface of the throat. However, when foil sheet (31) is inflated, no passages are formed between the foil sheet and the top surface of the mask. Again, the mask shown in Figures 28 and 29 is a mask with an integrated drainage tube. This drainage tube is not necessary in the mask according to the current invention, since a passage is provided between the lateral bellows and the top face of the mask portion.

Nothing in Brain '790 can overcome the deficiencies in Brain '956 in suggesting the claim 29 invention.

The examiner has rejected claims 1-10, 12 and 13 under 35 U.S.C. 103(a) as being unpatentable over Collins in view of Pagan, he has rejected claims 11 and 14-17 under 35 U.S.C. 103(a) as being unpatentable over Collins in view of Pagan and Brain '790, and he has

rejected claim 30 under 35 U.S.C. 103(a) as being unpatentable over Collins in view of Pagan and Cook. These rejections are also without merit.

The examiner states that Collins shows a mask where the airway tube and the intermediary portion are integrally moulded and the cuff portion is attached later on. The examiner also states that Pagan shows a mask where the cuff portion and the intermediary portion are integrally formed and the airway tube is added later on. The examiner then goes on to say that a combination of Collins and Pagan provide the invention as defined in claims 1-17.

The inventors disagree. Collins teaches that the airway tube must be stiff and the cuff part must be flexible. The problem is therefore how to manufacture the mask such that this difference in stiffness is achieved. Collins teaches that the airway tube and the cuff part are made from two different materials (see Collins at column 1, lines 54-55, and column 2, lines 9-10).

Pagan solves the same problem in the same way, namely the cuff part and the airway tube are made from two different materials. In Collins the intermediary portion is connected to the airway tube resulting in a stiff intermediary portion, while in Pagan the intermediary portion is attached to the cuff, resulting in a more flexible intermediary portion. However, there is no reason for a person of ordinary skill in the art to

combine the two documents since they both teach that the airway tube and the cuff part should be made from different materials. A person of ordinary skill in the art would therefore not be inspired to make a mask where the airway tube and the cuff part were made from the same material since both Collins and Pagan teach away from this mask.

The mask which the current application discloses has an airway tube and a cuff part of the same material, but with different wall thicknesses to provide the required stiffness to the airway tube and to provide the required flexibility to the cuff part. This is not disclosed nor anticipated by either Collins, Pagan or any combination thereof.

Nothing in Cook would overcome these deficiencies.

The examiner's rejections should be withdrawn.

The examiner has rejected claims 18-26 under 35 U.S.C. 103(a) as being unpatentable over Collins in view of Pagan and Hicks et al. This rejection is incorrect.

As noted previously, it would not be obvious to provide a mask where the cuff portion and the airway tube are integrally formed. Therefore, for the same reasons as discussed above with regards to claims 1-17, it would not be obvious to provide a method of manufacturing said mask.

Furthermore, it is noted that one of the steps of the method of claim 18 requires injection moulding of the airway tube, the intermediary portion as well as the cuff portion in a first step. In Collins, the airway tube and intermediary portion are formed in a first step and the cuff is added in a second step. In Pagan, the intermediary portion is injection moulded in a first step, the cuff is blow moulded in a second step and the airway tube is attached in a third step. In GB 2 367 525 (Hicks), the intermediary portion is moulded in a first step, the material for the cuff portion is injected in a second step, the cuff portion is inflated in a third step and the airway tube is added in a fourth step. It is, therefore, not clear how a person of ordinary skill in the art would arrive at a method according to the claim 18 where the airway tube, the intermediary portion and the cuff portion are all injection moulded in a single step.

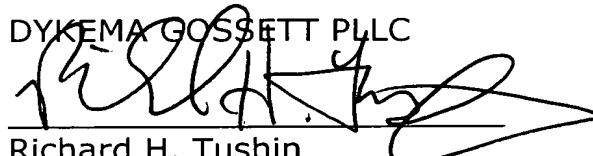
The examiner's rejection of claims 18-26 should be withdrawn.

Favorable reevaluation is requested.

Respectfully submitted,

By:

DYKEMA GOOSSETT PLLC


Richard H. Tushin
Registration No. 27,297
Franklin Square, Third Floor West
1300 I Street, N.W.
Washington, DC 20005-3353
(202) 906-8680